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01132-WI-hf**REMARKS*****Status of the Claims***

Claim 18 has been amended to more clearly focus attention on the claim issue at question for appeal, i.e. does the prior art teach the method of reducing sebum production? As this limitation has always been an essential element of the claim, no new search or consideration should be necessary. Claims 19 and 21 have been amended to correct a typographical error.

It is believed that no new matter has been added. Claims 18-47 are still pending.

35 U.S.C. 112, first paragraph rejection

The amendments to claim 19 and 21 are believed to render this issue moot. The remainder of the response to the 112, first paragraph rejection is for future *Festo* considerations should this application become involved in litigation and can be ignored by the Examiner if desired.

The applicants emphasize the fact that the amendments to claims 19 and 21 were made to merely correct a typographical error which arose when deletion of the phrase "consisting essentially of" from previous versions of the claim was made. The applicants intended these dependent claims to refer to "distarch phosphate **or** cyclodextrin" as claim 18 already encompassed the broader subject matter.

The applicants also emphasize that claims 19 and 21 could've remained unamended with the "distarch phosphate **and** cyclodextrin" language because:

- (1) there is no requirement for *ipsissimum verbis* support to show possession (see *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978));
- (2) there is no bar to the applicants claiming less than the full scope of the invention to which they are entitled; and
- (3) independent claim 18 specifically recited "and mixtures thereof" of which "distarch phosphate **and** cyclodextrin" would be considered a part thereof.

As such, the applicants believe that the Examiner did not meet the burden prescribed for establishing lack of written description or lack of possession to overcome the strong presumption that an adequate written description was presented at the time of filing. MPEP 2163, section I. A. states:

There is a **strong** presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the

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disclosure a description of the invention defined by the claims."). - emphasis added by applicants.

see also *In re Eickmeyer*, 202 USPQ 655, 662 (CCPA 1979) - "To satisfy the description requirement of section 112, first paragraph, an application must contain sufficient disclosure, expressly or inherently, to make it clear to one skilled in the art that the appellant was in possession of the subject matter claimed...[A] statement of the appellant's invention [in his specification] which is as broad as appellant's broadest claims' is sufficient to meet this requirement."

For these reasons, the applicants believe the written description rejection was made in error and should not be given any weight in determining the range for doctrine of equivalents.

35 U.S.C. 102(b) rejection

Claims 18, 20, 36-39 and 45-47 were rejected by the Examiner as being anticipated by Gettings et al. (U.S. Patent 4,908,355 - hereinafter "Gettings"). The applicant request reconsideration of this rejection in light of the comment that follow.

MPEP 2131 states that "A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Gettings does not teach every element of the applicants' invention.

While Gettings relates to a method treating acne, their method of doing so is by "...including an antibacterially effective amount of a silane and a water immiscible liquid, causing silane to penetrate follicular orifices, driving the silane into sebaceous glands, and destroying members of the staphylococcal (sic) group of bacterial (sic) therein." (see col. 3, lines 59-66). Regardless of whether the applicants' amendment is entered, the key element of their invention as claimed is the reduction of sebum production. There is nothing within the Getting reference which teaches or suggests that they achieve their anti-acne effect by reducing sebum production.

Although no mention of inherency was made by the Examiner, it is noted that should there be a rationale that Gettings inherently teaches the reduction of sebum production, the burden lies with the Examiner to show that this is true. see MPEP 2112, sec. IV (Requirements of Rejection Based on Inherency; Burden of Proof) states "The fact that a certain result or characteristic may occur or be present

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in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)....To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Therefore, the applicants present that Gettings does not anticipate the applicants' invention as claimed.

35 U.S.C. 103(a) rejections

- (1) Claims 40-44 were rejected by the Examiner as being obvious over Gettings, *id.* The applicants request reconsideration of this rejection in light of the comments that follow.

The applicants response to the 102(b) rejection made above also applies here. With regard to the point that "optimal or workable concentration of the antiperspirant actives by routine experimentation is obvious and within the skill of the art.", this proposition does not apply to the current fact pattern.

MPEP 2144.05 section II (Optimization of Ranges) states that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)." There is no recognition by Gettings that the amount of "antiperspirant actives" is a results effective variable for their method of treating acne.

The only critical elements to achieve Gettings method of treating acne is the presence of a silane and a water immiscible liquid (i.e. a polysiloxane). Elements such as the acidic aluminum/zirconium salt and the amounts thereof claimed by the applicant in claim 40 are optional ingredients in Gettings and as such would not be viewed as a results-effective variable when considering the Gettings reference as a whole.

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- (2) Claims 19 and 21-26 were rejected by the Examiner as being obvious over Gettings, *id.* in view of Müller et al. (WO 98/01109 - English language equivalent - U.S. Patent 6,248,338 - hereinafter "Müller") and Dodd et al. (U.S. Patent 6,656,456 - hereinafter "Dodd").

The applicants response to the 102(b) rejection over Gettings made above also applies here. It is noted that neither of the references teach that either di-starch phosphate or cyclodextrin to be an agent for the reduction of sebum which is not necessarily fatal to their use as the motivation for combining the references need not be the same as that described by the applicants. However, there is no teaching, suggestion or direction for one of ordinary skill in the art to pick the required elements from within the teachings of Müller and/or Dodd and combine them with the teaching of Gettings.

The useful properties ascribed to the starch derivatives of Müller are disclosed within the context of making starch derivatives which are suitable for use in aqueous solutions. see col. 3, lines 36-38 and 41-43 - "A decisive feature of the invention is that the starch derivative is pregelatinized...Pregelatinized starches or starch derivatives are soluble in cold water without cooking." In addition, the state of the art with regard to starches was disclosed by Müller not to be uniform. see col. 4, lines 1-8 - "It has surprisingly been found that with a cooking starch (i.e., non-gelatinized starch) modified in the same way as a starch to be used according to the invention, the desired advantages regarding rheology, skin feel and emulsion stability are not obtained even if the aqueous phase, following addition of the cooking starch, is heated for 15 minutes to a temperature above the gelatinizing temperature of the starch." However, the compositions used in Gettings comprise of silanes and water-immiscible liquids or silicone fluid. There is no teaching or suggestion or expectation of success for imbuing the composition of Gettings with the properties associated with the starches of Müller when used in a water-immiscible liquid as opposed to an aqueous solution.

Similarly, Dodd's teaching of cyclodextrins are taught as being part of an "aqueous gel composition" whereas Gettings teaches using a composition comprising a silane and a water immiscible liquid. Apart from the difficulty of isolating Dodd's teaching of a cyclodextrin (at least Müller described di-starch phosphate as being a particularly preferred embodiment in an invention specifically directed to starch derivatives), one of ordinary skill in the art would not look to a reference directed toward aqueous gel compositions to determine how a water immiscible composition is to be modified.

Even if the references are taken as a collective whole without regard to designations of "primary"

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and "secondary" reference, one of ordinary skill in the art having the references before them but without the benefit of the applicants' claims before them as does the Examiner, would not be able to pick out the essential elements of the applicants claimed invention without undue experimentation. Therefore, the invention cannot be held to be *prima facie* obvious.

- (3) Claims 27-35 were rejected by the Examiner as being obvious over Gettings, *id.* in view of Kropf et al. (U.S. Patent 6,316,030).

The applicants response to the 102(b) rejection over Gettings made above also applies here. With regard to the assertion that aluminum hydroxyacetate and aluminum chlorhydrate likely have equivalent properties, this point is conceded.

Closing

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (10 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 15 October 2004

By: Agata Glinska
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